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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,385	06/27/2005	Ulrik Darling Larsen	ALB.016	4378

20987 7590 10/28/2008

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EXAMINER	
CHAN, CEDRIC A	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,385	LARSEN, ULRIK DARLING	
	Examiner	Art Unit	
	Cedric A. Chan	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30 and 32-56* is/are rejected.

7)☒ Claim(s) *31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/10/2004, 2/16/2005, 4/18/2008, & 8/26/2008.

DETAILED ACTION

1. The preliminary amendments to the Specification and the Claims, both dated December 10, 2004, are hereby acknowledged. Claims 1-28 have been canceled; claims 29-56 are pending.

Claim Objections

2. Claims 31 and 54 are objected to because of the following informalities: Claim 31 recites "a second sampling member" in addition to the "first sampling member" of claim 29. Examiner recommends that Applicant amend claim 31 to distinguish the first and second sampling members, and the limitations associated with their positioning. For instance, Examiner suggests that "the member" (claim 31, line 9) be modified to refer explicitly to the second sampling member.

With regard to claim 54, the repeated phrase "with the," recited in line 4, should be deleted.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 30, 34, 36-41, 43, 48-52, 55, and 56** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the cartridge according to claim 29, but adds functional limitations associated with the movable first sampling member that render the invention

indefinite. Specifically, claim 30 recites that "in the second position the first cavity is in communication with the first mixing chamber for *entrance* of liquid from the first mixing chamber into the first cavity" (emphasis added). This "second position" phenomenon appears to contradict the "second position" phenomenon introduced in claim 29, i.e. "in a second position the first cavity is in communication with the first mixing chamber for *discharge* of the liquid sample into the first mixing chamber" (emphasis added). Since claim 30 does not further structurally limit the sampling member introduced in claim 29, it is unclear how the recited contradictory phenomena are able to occur. Clarification/corrections required.

Examiner also suggests that Applicant indicate in claim 30 that "the second position" and the "third position" are associated with positioning of the first sampling member.

The limitations "second particle characterization means" and "second mixing chamber" and "second collection chamber" recited in claim 34 lack sufficient antecedent basis.

Claim 36 recites "a second liquid storage chamber," but the cartridge according to claim 29 does not include any liquid storage chamber.

Claim 36 also recites "the...second cavity" and "the second mixing chamber." Claim 37 recites "the ... second orifice." These limitations lack sufficient antecedent support. Appropriate correction required.

It is not possible to determine what "the respective collection chamber" is, because neither claim 38 nor claim 37 before it defines the relative relationships

between the "input" and the "respective collection chamber." The claim(s) need to adequately link the "input" to its "respective collection chamber." Also, since claim 29 only recites a "first collection chamber," it is unclear what "the respective collection chamber" is. Is this a new chamber, or plural distinct chambers? Furthermore, claim 38 recites that "presence of liquid is detected at the input and at the output" but the structural feature which performs said detection is undefined. Is "presence" detection performed by a structure associated with the housing/cartridge, by a separate detection device, or a combination of the two?

Claim 39 recites "a secondary electrode positioned at the input," as well as "a further secondary electrode positioned at the output." However, the invention as laid out in claim 39 does not include primary electrodes. Are "primary" electrodes required in order to make the device function as desired? What purpose do the claimed secondary electrodes serve? Are "secondary" electrodes structurally and functionally distinct from other (e.g., "primary") electrodes? Clarification and appropriate corrections required.

The limitations "the mixing chambers" and "the collection chambers" recited in claim 41 imply multiple mixing chambers and collection chambers, however only "a first mixing chamber" and "a first collection chamber" are recited in claim 29. Thus, the "mixing chambers" and the "collection chambers" recited in claim 41 lack sufficient antecedence. This applies similarly to "the respective orifice," since only a "first orifice" is claimed prior to recitation of that limitation. Claim 41 should furthermore be clarified, because it is not clear whether the limitation, "substantially less than" is intended to

modify "transverse cross-sectional area" or "the level." Applicant must also adequately define "the height of the chamber above the respective orifice. "Height" is a dimension that can be interpreted to have different meanings. One's interpretation of "height" can vary, for example, depending on the orientation of the claimed device. Applicant must specify in the disclosure the precise meaning of the word "height" in the context of the instant invention. Applicant should also distinctly point out in the claims the orientation of the device. Because of these deficiencies, it is impossible to possible for one to ascertain the scope of the limitation "above the respective orifice." The term "transverse" is also related to orientation, and is likewise indefinite. Appropriate correction required.

The term "blood sample" recited in claim 43 lacks sufficient antecedent support. Note, claim 29 only recites "a liquid sample," and does not specifically require the liquid sample to be "blood." Appropriate correction required.

Claim 44 recites that "a mixing member is positioned in at least one of the mixing chambers," but claim 29 recites only one (i.e., a "first") mixing chamber. Thus, "the mixing chambers" in claim 44 lacks sufficient antecedent basis.

The "second collection chamber" in claim 48 lacks sufficient antecedent support. Claim 29 only teaches a "first collection chamber," so it is unclear what the "second collection chamber" recited in claim 48 is intended to refer to. Moreover, the phrase "respective orifice" is indefinite because the claims fail to distinctly point out the relationships between said collection chambers and orifice(s).

Claim 51 recites "the first storage chamber" and "the second cavity." Both of these limitations lack sufficient antecedent basis.

In claim 52, the limitations "first storage chamber" (line 8) and "second storage chamber" (line 13) lack sufficient antecedent basis. Furthermore, claim 52 recites the step of "making particle characterizing measurements," but fails to identify which particle characterizing means are being used to conduct said measurements (in the cartridge according to claim 31, there are two distinct particle characterizing means). Clarification is required.

In claim 55, the limitation, "the second particle characterization means" lacks sufficient antecedent basis. In claim 56, "the second collection chamber" and "the second orifice" lack sufficient antecedent basis. Appropriate correction required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 29, 32, 35, 43, 46-51, and 53** are rejected under 35 U.S.C. 102(b) as being anticipated by Berndtsson (US Patent 6,387,328).

Berndtsson teaches a disposable sampling device (cartridge) and an apparatus for counting particles contained in a liquid, including a solid block-shaped housing connectable to the apparatus. The housing has a member for introducing a sample

therein, a device for metering a defined volume of the sample, and a chamber for containing a defined volume (V) of a diluting liquid (see Abstract).

The device comprises a substantially block-shaped housing (i.e., body 40), said body including therein a first mixing chamber (i.e., volume space 61) and a first collection chamber (i.e., conical recess 59) separated by a wall containing a first orifice (see col. 5, l. 18-24).

In the housing, there is provided a reagent storage chamber or first storage chamber, i.e. cylinder (44). A piston (47) is axially movable within the cylinder by means of a piston rod (48) accessible from outside the housing, the upper end (48) of the (first) reagent storage chamber (44) being connected to a channel (49) provided in the housing (see col. 3, l. 40-47). The first storage chamber (i.e. reagent storage chamber) is in communication with the first cavity (valve chamber 52) of the first sampling member so that liquid can be communicated from the liquid storage chamber through the first cavity, and into the first mixing chamber (i.e., space 61). A volume (V) of the reagent storage chamber (44) is filled with a liquid (L), such as a diluting liquid. Furthermore, Berndtsson states that the volume (V) is defined by the piston (47) in an axial position thereof where it covers the mouth of the channel (63).

In the housing there is also provided a first movable sampling member, i.e. turning valve (50) having a valve body (51) that is rotatable within a first cavity, i.e. cylindrical valve chamber (52). An actuating means, such as a diametrically extending slot or two diametrically opposed holes (51'), is provided to rotate the movable sampling

member from outside the housing. A through channel 53 extends across the valve body which is positionable in two different positions (col. 3, l. 49-55).

The first sampling member described above can be positioned according to claim 29 (see Figs. 2, 3-9,10, or 11). In a first position, the through channel communicates with an intake channel (54) in the housing opening in a sample receiving bore, i.e. aperture (55) in the front wall and a sucking channel (56) leading to a sucking means in the shape of a diaphragm pump (57) having a resilient diaphragm (58) covering the conical recess (59) in the upper wall (41). In a second position (shown in FIGS. 5-8), the through channel communicates with the channel from the cylinder (44) and with a channel (60) leading to the bottom of the first mixing chamber, i.e. volume space (61) (col.3, l. 55 thru col. 4, l.3).

The cartridge also includes several connectors for docking the cartridge to the docking station (apparatus 84 shown in Figs. 12 and 13) and enabling electrical and fluid connections when the cartridge is received in the docking station. Specifically, in the channel (63) there is a capillary (64) and on either sides thereof an electrode (65, 66) connected to a respective conductor (67, 68) terminating in a respective terminal (69, 70). In the channel (63) there are also two detectors (71) and (72) having signal transmitting conductors (73,74), respectively, terminating in respective terminals (75,76) in the bottom wall of the cartridge. The detectors (i.e., "first particle characterizing means", also, "sensor") may, e.g., be optical detectors, and in such case the conductors (73, 74) are optical fibres. Also possible is that the detectors are capacity sensitive detectors, and in such case the conductors (73, 74) are electric conductors. In any

case, the detectors are adapted to start and stop, respectively, the particle counting operation (see col. 4, l.4-15). Berndtsson further specifies that the sensor component (i.e. detector) may specifically be adapted to have a light sensor (93) to conduct photometric measurements (see col. 6, l. 15-22).

Regarding claims 48 and 49, a piston-actuated pumping mechanism is used to induce mixture of reagent (L) with sample (S). In Fig. 8, the piston pump chamber is in communication with chamber/space 61, which (since mixing is occurring in this case in the pump chamber i.e. cylinder 44) may serve as the device's 'first' collection chamber. Regarding claim 50, Berndtsson teaches a diaphragm (i.e. membrane) actuated pump (57) (see col. 3, l. 60).

Berndtsson also teaches the apparatus recited in claim 53, including the cartridge of claim 29 per the above discussion, as well as a counting apparatus (84) with a docking station (i.e. "base instrument" – see Fig. 12) having connectors for electrical and fluidic connections which enables particle characterization (counting) when the cartridge is received in the docking station at the provided means for docking/receiving of the cartridge, i.e. the receiving slot (85) (see col. 6, l. 7-14).

In accordance with the structural features of the cartridge and apparatus discussed above, Berndtsson further teaches a method of operating said apparatus/cartridge corresponding to the invention set forth in claim 51. Briefly, Berndtsson's method includes the following steps: first, a volume (S) of blood is sampled from a human patient. In the first step, the first sampling member, i.e. valve body (51), is positioned in a 'first' position such that blood is allowed into the cartridge.

The cartridge is then connected to an a-centrally located particle counting apparatus (84) (col. 4, l. 47-48). The valve body (51) is rotated to its second position (shown in Fig. 5), and then actuation/displacement of the piston (47) causes the liquid (L) contained in the reagent storage chamber (i.e., the first storage chamber) to flow through channel 49 (displacing a sample of blood contained therein), and mix with the blood sample in the mixing chamber (i.e., space 61) (see col. 4, l. 55-60). Once the sample reaches the detector (sensor), the particle characterization is conducted. After sample characterization, the cartridge may be disconnected from the counting apparatus 84, and disposed. For additional details regarding Berndtsson's method of operation, Applicant is referred to col. 4, l. 35 thru col. 5, l. 30 of Berndtsson's disclosure.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 30, 34, 41, 44, 45, and 55** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berndtsson (US Patent 6,387,328) in view of Gorin et al. (US Patent 5,077,017).

Berndtsson teaches the structural features listed in claim 29, but does not teach a cartridge having a second mixing chamber separated from a second collection chamber by a second orifice, or second particle characterizing means.

Gorin et al. (hereinafter, "Gorin") teach several embodiments of a dilution and mixing cartridge, including one embodiment comprising multiple mixing chambers, multiple collection chambers, and multiple particle characterization means. The embodiment depicted in Fig. 5 is a cartridge in which multiple analyses can be carried out, said cartridge comprising multiple measuring chambers (532, 532', 532") and reagent storage containers (first, second, and third storage chambers, i.e. diluent application sites 520, 520', 520"). First and second mixing chambers (540, 570) are also provided. It is noted that if there are multiple measuring chambers, then there are clearly then multiple (e.g., first, second, third, etc.) measuring (characterizing) means (see col. 14, l. 43-65).

Inspection of Berndtsson's device as depicted in Fig. 2 (for example) shows that it would not only have been simple to modify the fluidic arrangement in the cartridge with these secondary features taught by Gorin, but it would have obvious to one of ordinary skill in the art to do so. Gorin teaches multiple sets of measuring, collection, and mixing chambers in order to enable the performance of "several analyses" using one cartridge.

It would have been obvious to one of ordinary skill in the art to provide Berndtsson's device with the secondary fluidic arrangement recited in instantly presented claim 30, in order to perform multiple analyses using the same cartridge. Such a modification would allow for a third valve position per claim 30. It would have been obvious to provide such a third valve position, in order to allow for control of multiple fluid samples (including different reagents and/or different dilutions) using one valve instead of a plurality of valves.

Regarding claims 34 and 36, it would have been obvious to modify Berndtsson's device to include second mixing and collection chambers for the reasons previously discussed. With further regard to claim 34, it was discussed previously that Berndtsson's device comprises a capillary wherein two electrodes (i.e., a first electrode 65 and a second electrode 66) are provided on either sides of the capillary, each electrode being connected electrically to a respective terminal (terminals 69 and 70) that are accessible from the outside of the cartridge.

Regarding claim 41, Berndtsson teaches the limitations of claim 29, but does not specifically disclose mixing and collection chambers having the geometric properties recited (i.e., chamber transverse cross-sectional area substantially smaller at the orifice junction than at 'higher' levels).

Gorin suggests such a configuration in patent '017, for creating a natural "stop flow junction." This type of junction, Gorin explains, "is not a traditional valve as it has no moving parts. Rather, this junction relies on backpressure from the surface tension of the liquid sample to stop flow." Backpressure is created, for example, "when the

cross-sectional area of the flowpath increases in a region in which there is contact between the liquid and the container walls (e.g., when a small tube enters a larger chamber or when the cross-sectional area of a channel increases). Greater backpressure and more consistent operation is achieved when the increase in cross-sectional area of the flowpath is abrupt rather than gradual (col. 6, l. 37-50).

It would have therefore been obvious to one of ordinary skill in the art to provide the cartridge of Berndtsson with mixing and collection chambers configured according to the teaching of Gorin, in order to achieve greater backpressure and thus a greater amount of fluid flow control within the cartridge.

Regarding claims 44-45, Berndtsson teaches the limitations of claim 29, but does not specifically disclose a magnetic mixing member to be placed in the mixing chamber.

Gorin teaches another embodiment of the invention previously described, as shown in Fig. 12A. Mixing in this embodiment of Gorin's mixing and dilution cartridge occurs in the mixing chamber (740), below which is provided a recess (747). The recess 747 allows close approach of a magnet or other means to activate a stirring bar or plate retained in chamber 740.

It would have been obvious to one of ordinary skill in the art to incorporate a mixing member such as Gorin's stirring bar/plate into the mixing chamber of Berndtsson, in order to achieve highly efficient and effective mixing of sample/reagent solutions within the mixing chamber. It would have been obvious to provide a magnetic mixing member as taught by Gorin, because magnetic mixing members allow controllable direct mixing of fluids without the need for the space-consuming mechanical

actuators or expensive and less-effective non-contact mixing mechanisms like piezoelectric/ultrasonic mixing devices.

Regarding claim 55, Berndtsson teaches the limitations recited in claim 53 but does not specifically teach a second particle characterization means (or the required docking station connectors).

It would have been obvious to modify Berndtsson's device to include second particle characterizations means for the reasons previously discussed. Moreover, it would have been obvious to one of ordinary skill in the art to provide docking station connectors for the second characterization means, just as Berndtsson taught with respect to the first characterization means, because adding such connectors would allow the second characterization means to be powered directly by the docking station.

10. **Claims 37-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berndtsson (US Patent 6,387,328) in view of Besemer et al. (US Patent 5,104,813).

Berndtsson teaches the structural features of claim 29, as discussed above. However, Berndtsson does not specifically disclose a volume metering means per claims 37-40 of the instant invention.

Besemer et al. (hereinafter, "Besemer") teach a dilution and mixing cartridge comprising various optical and/or other types of sensors for detecting the presence of liquids or analytes in various mixing and/or measuring chambers of the cartridge (col. 15, l. 20-26). For example, sample entering a flow chamber can be detected optically by detecting light at a location adjacent the sample entrance (input). Taking such an

observation at the input allows for control of operational timing of the analytical apparatus (see col. 16, l. 10-20). Detectors might instead be placed at opposite sides of the cartridge in order to detect when fluid has reached the end of, for example, a measuring chamber 240 (see col. 18 l. 60 thru col. 19, l. 3).

With regard to claims 37, 38 and 40, it would have been obvious to incorporate the optical fluid presence detector taught by Besemer into the cartridge of Berndtsson, in order to achieve operational timing control or to control the delivery of reagent and/or sample according to the presence of fluid already in the cartridge.

Berndtsson does not teach using electrodes as fluid presence detectors, but does teach the use of electrodes for counting particles. It is well known in the art that electrodes can be used to detect electrical characteristics of a fluid such as impedance, resistance, etc. Furthermore, routineers in the art commonly use electrodes as sensors. In Berndtsson's device, for example, electrodes are used to count particles. Thus, with specific regard to claim 39, it would have been obvious to modify the combined invention of Berndtsson/Besemer as applied to claim 38, by providing electrode detection instead of optical detection means. Such a modification would have been obvious to one of ordinary skill in the art, because electrodes are commonly known for measuring/detecting particles, and using electrodes instead of an optical system eliminates the need for additional light sources and detectors.

11. **Claim 42** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berndtsson (US Patent 6,387,328) in view of Kelley (US Patent 5,257,984).

Berndtsson teaches the structural features of claim 29, as discussed above. However, Berndtsson does not specifically teach a first cavity comprising an anti-coagulation reagent.

Kelley teaches a blood collecting device for transferring a blood specimen from a droplet source to a collection tube via a capillary tube (Abstract). The blood collection device (22) comprises a short cylindrical tube (24) and a glass capillary tube (36), said capillary tube (36) having an anti-coagulant coating on its inner surface using, for example, heparin or EDTA anti-coagulants (col. 3, l.1-6).

It would have been obvious to one of ordinary skill in the art to provide the first cavity in Berndtsson's device with an anti-coagulant coating like Kelley teaches in '328, in order to prevent coagulation of blood after it is sampled while it is being contained within the holding cavity.

12. **Claims 33 and 54** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berndtsson (US Patent 6,387,328) in view of Feistel (US Patent 6,426,230).

Berndtsson teaches the structural features of claim 32, as discussed above. However, Berndtsson does not specifically teach a breakable seal separating the reagent chamber from the first mixing chamber.

Feistel teaches several embodiments of a disposable diagnostic device for conducting a diagnostic test on a sample. The device includes a substantially planar, flexible article, a channel formed within the article, at least one fluid-receiving compartment formed within the article and fluidly connectable to the channel, and a

solid phase movably positioned within the channel (Abstract). Generally, the device comprises: an article (such as a laminate) which has a channel (25) formed therein that extends along the length of the laminate from a sample transfer end (26) to a test result end (27). Along the length of the channel (25) are several fluid-receiving chambers (e.g., compartments 35 and 40) which are fluidly connectable to the channel (25). At least one of these compartments is pre-filled with a liquid such as a reagent, tracer, etc. The pre-filled compartment (35) is fluidly connectable to the channel (25) via a passage (37). Fluid (36) within the compartment (35) remains in the compartment until pressure is externally applied to the compartment by a peristaltic force. The pressure causes a breakable seal (38) to rupture, releasing the fluid (36) into the channel (col. 4, l. 29-46).

It would have been obvious to provide a breakable seal as taught by Feistel to separate the reagent chamber from the first mixing chamber in the invention of Berndtsson, in order to prevent accidental leakage of stored reagent prior to use of the device.

With regard to claim 54, Berndtsson teaches the structural features of claim 53, but does not specifically teach a docking station comprising a port for forming a gas connection with the cartridge port when the cartridge is received in the docking station.

Feistel teaches embodiments of device (10) wherein the channel can include an air vent that is connectable to an external source of gas for applying drying gas, e.g., air, to the solid phase (col. 2, l. 20-29). The device can include a dual purpose vent system that allows displacement of air within the chambers, as well as introduction of air for purging and drying situations. The dual purpose vent (150) provides an output for air

within the channel (25), as well as an input for external gases that may be necessary for conducting a particular diagnostic test (col. 7, l. 13-27).

Additionally, Feistel provides the device (10) with attachment holes (85) for mounting device 10 during a diagnostic test to, for example, a diagnostic test machine capable of applying and controlling the required peristaltic forces, and detecting the test results.

It would have been obvious to one of ordinary skill in the art to provide modify the invention of Berndtsson with a gas port as taught by Feistel, in order to allow (for example) injection of drying and/or purging gas. It would have been obvious to provide the docking station taught by Berndtsson with a gas connection port, in order to supply air/gas to the cartridge during a particle characterization operation.

13. **Claim 56** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berndtsson/Gorin as applied to claim 55 above, and further in view of Feistel (US Patent 6,426,230).

With regard to claim 56, Berndtsson/Feistel (as discussed previously) features the structural elements recited in claim 55, but the combined invention does not include a docking station comprising a port for forming a gas connection with the cartridge port when the cartridge is received in the docking station.

Feistel teaches embodiments of device (10), as previously discussed, wherein the channel can include an air vent that is connectable to an external source of gas for applying drying gas, e.g., air, to the solid phase (col. 2, l. 20-29). The device can

include a dual purpose vent system that allows displacement of air within the chambers, as well as introduction of air for purging and drying situations. The dual purpose vent (150) provides an output for air within the channel (25), as well as an input for external gases that may be necessary for conducting a particular diagnostic test (col. 7, l. 13-27).

Additionally, Feistel provides the device (10) with attachment holes (85) for mounting device 10 during a diagnostic test to, for example, a diagnostic test machine capable of applying and controlling the required peristaltic forces, and detecting the test results.

It would have been obvious to one of ordinary skill in the art to provide modify the combined invention of Berndtsson/Gorin with a gas port as taught by Feistel, in order to allow for injection of drying and/or purging gas. It would have been obvious to provide the docking station in the combined invention of Berndtsson/Gorin with a gas connection port, in order to supply air/gas to the cartridge during a particle characterization operation.

Allowable Subject Matter

14. Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: claim 31 recites, adds a second mixing chamber, second collection chamber, a second wall separating said second mixing and collection chambers, a second orifice,

second particle characterization means, and in particular, "a second sampling member ... having a second cavity for receiving and holding ... sampled liquid." The second sampling member in claim 31 is not taught nor fairly suggested by the prior art made of record. Moreover, the second sampling member is specially related to said chambers such that, "in a first position, the second cavity is in communication with the first mixing chamber for entrance of liquid from the first mixing chamber into the first cavity, and, in a second position, the second cavity is in communication with the second mixing chamber for discharge of the sampled liquid in the second cavity into the second mixing chamber."

While claim 30 recites many of the same secondary features, claim 30 differs from claim 31 because claim 30 does not recite a "second sampling member...having a second cavity." It is held that the prior art fairly suggests the addition of fluidic features such as secondary chambers, such that it would have been obvious to any person of ordinary skill in the art to provide such modifications. It would be obvious for one to attempt to maximize the utility of the prior art, and so addition of chambers and particle characterization or measuring means to the same valve system would not constitute a patentable improvement over the cited art.

However, the addition of the second sampling member with corresponding second cavity in claim 31 provides an additional level of complexity that the prior art does not appear to suggest. This added complexity in claim 31 results in novel and un-obvious fluidic relationships between the sampling member and the various chambers in

the system. Thus, claim 31 (if corrected for unresolved minor informalities) would be allowable over the prior art.

16. Claim 52 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shartle et al. (US Patent 5,230,866) teaches a self-contained dilution apparatus with capillary stop-flow junctions for providing reproducible dilution of samples.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cedric A. Chan whose telephone number is (571) 270-3721. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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CC

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October 25, 2008